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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,770	09/28/2001	Ronald J. Solar	20098.07	3448

7590 11/13/2002

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EXAMINER

HO, UYEN T

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 11/13/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/965,770

Applicant(s)

SOLAR ET AL.

Examiner

(Jackie) Tan-Uyen T. Ho

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14, 16-30 and 32-37 is/are rejected.
- 7) ☒ Claim(s) 15 and 31 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Specification*

1. The abstract of the disclosure is objected to because it contains a phrase, which can be implied, for example, "a device of the present invention" in line 1. Examiner suggests that "the present invention" should be deleted from the abstract. Correction is required. See MPEP § 608.01(b).

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-5, 10-14, 16-22 and 26-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Kalis (5,609,624).

In regard to claims 1-5, 16-21 a stent for insertion into a vessel including:

- a stent body having proximal and distal ends and an outer surface,
- at least three longitudinal projection external to the stent outer surface wherein the projections extend from the proximal to distal ends and are equidistantly spaced around the circumference of the stent,
- a generally circular cross-section.

In regard to claims 6 and 22, the distal end of a projection is tapered in a radial direction as the projection having a triangular cross-sectional shape (fig. 2d).

In regard to claims 10 and 26, wherein the projection inherently acts as stress concentrator, as claimed.

In regard to claims 11 and 27, the projections have a circular cross section (fig.1).

In regard to claims 12 and 28, wherein the projections are formed integral with the stent wall surface (fig. 1).

In regard to claims 13-14 and 29-30, the projections are flexible and attached to the stent wall surface (fig. 1).

**Note:** The introductory statement of intended use and all other functional statements have been carefully considered but are deemed not to impose any structural limitations on the claims distinguishable over the Kalis's graft which is capable of being used as a stent of as claimed if one desires to do so.

#### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 7-9 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kalis '624 in view of Andersen et al. (5,674,276). Kalis does not disclose how the stent (10) being expanded. Andersen et al. disclose a stent (10) being expanded by a balloon or self-expanding (col. 9, lines 4-16). Therefore, it would have been obvious

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matter of design choice to modify the Kalis reference by having the stent as self-expanding or balloon expandable, since applicant has not disclosed that having the self-expanding or balloon expandable stent solves any stated problem or is for any particular purpose and it appears that the stent would perform equally well with its characteristic as self-expanding or balloon expandable.

6. Claims 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kalis '624 in view of Andersen et al. '276. Kalis disclose all the limitations of a stent adapted to support a defected portion of a vessel, as claimed. However, Kalis does not disclose a method of using the stent for support a portion of a stenosis, as claimed in claims 32-37. Andersen et al. disclose a method of supporting a portion of a stenosis by a stent (fig. 7d). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the method of Andersen et al. to carry out the function of the Kalis's stent in order to treat a defected portion of a vessel.

***Allowable Subject Matter***

7. Claims 15 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art fails to disclose or suggest a longitudinal projection external to a stent outer surface and wherein the longitudinal projection has a helical configuration.

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**Conclusion**

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Phan et al. (5,129,910) and Holman et al. (6,059,823) disclose a stent having a body and a helical projection extending from proximal to distal end of the stent.

Mitchell et al. (6,214,037) disclose a stent having a body and longitudinal projections (figs. 3-6).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is (703) 306-3421. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



(Jackie) Tan-Uyen T. Ho  
November 6, 2002



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